Notic of Allowability	Application N .	Applicant(s)	
	09/813,279	WOOD ET AL.	
	Examiner	Art Unit	
	Louise N. Leary	1654	

-- The MAILING DATE of this communication appears on the c ver sheet with the c rrespondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *request for continued examination and IDS filed 11-29-2004*.

2. ☒ The allowed claim(s) is/are *1-64*.

3. ☒ The drawings filed on *01 March 2001* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) f each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 11-29-04
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

LOUISE N. LEARY
PRIMARY EXAMINER

1. The following is an examiner's statement of reasons for allowance:

The reasons for allowance of the claims is that none of the prior art of record disclose or suggest (1) a method of detecting ATP in a sample comprising (a) adding to the sample a reagent composition comprising one or more detergents and a luciferase, with the proviso that, wherein the reagent composition maintains at least about 30% activity, as measured by luminescence after the reagent composition is combined with the sample, for at least one hour compared to the reagent composition's activity just after the luciferase is combined with the one or more detergents, and with the proviso that wherein the one or more detergents present in the reagent composition are collectively able to reduce ATPase activity endogenous to the sample by at least about 25% relative to the sample's ATPase activity in the absence of the one or more detergents; and (b) detecting luminescence; nor (II) a method as described above in step (a) and (b) quantifying luminescence; (III) a method of measuring cell viability within a population of cells comprising (a) contacting the population of cells with a reagent composition comprising one or more detergents and a luciferase, with the proviso that, wherein the reagent composition maintains at least about 30% activity, as measured by luminescence after the reagent composition is combined with the sample, for at least one hour compared to the reagent composition's activity just after the luciferase is combined with the one or more detergents, and with the proviso that wherein the one or more detergents present in the reagent composition are collectively able to reduce ATPase activity endogenous to the sample by at least about 25% relative

to the sample's ATPase activity in the absence of the one or more detergents; and (b) detecting luminescence with the proviso that wherein the amount of luminescence detected is proportional to the viability of the cells within the population; nor (IV) a method of determining the effect of a compound on a first population of cells comprising (a) contacting the first population of cells with a concentration of the compound; (b) subsequently contacting the first population of cells with a reagent composition comprising one or more detergents and a luciferase, with the proviso that, wherein the reagent composition maintains at least about 30% activity, as measured by luminescence after the reagent composition is combined with the sample, for at least one hour compared to the reagent composition's activity just after the luciferase is combined with the one or more detergents, and with the proviso that wherein the one or more detergents present in the reagent composition are collectively able to reduce ATPase activity endogenous to the sample by at least about 25% relative to the sample's ATPase activity in the absence of the one or more detergents; and (c) detecting an amount of luminescence and (d) comparing the amount of luminescence in the first population to an amount of luminescence in a second population of cells; nor (V) a method of detecting ATP in a sample comprising (a) adding to the sample a reagent composition comprising one or more detergents and a luciferase, with the proviso that wherein the luciferase comprises an amino acid sequence selected from the group consisting of SEQ ID NOs: 1, 2, 3, and 4, wherein the reagent composition maintains at least about 30% activity, as measured by luminescence after the reagent composition is combined with the sample, for at least one hour compared to the reagent

composition's activity just after the luciferase is combined with the one or more detergents, and with the proviso that wherein the one or more detergents present in the reagent composition are collectively able to reduce ATPase activity endogenous to the sample by at least about 25% relative to the sample's ATPase activity in the absence of the one or more detergents; and (b) detecting luminescence; (VI) a method of detecting ATP in a sample comprising (a) adding to the sample a reagent composition comprising one or more detergents and a luciferase, wherein the reagent composition further comprises NaF, with the proviso that wherein the one or more detergents present in the reagent composition are collectively able to reduce ATPase activity endogenous to the sample by at least about 25% relative to the sample's ATPase activity in the absence of the one or more detergents; and (b) detecting luminescence; nor (VII) the method described in step (a) of (VI) above and (b) quantifying luminescence; nor (VIII) the method described in step (a) of (VI) above and (b) detecting luminescence, wherein the amount of luminescence detected is proportional to the viability of the cells within the population; not (IX) a method of determining the effect of a compound on a first population of cells comprising (a) contacting the first population of cells with a concentration of the compound; (b) subsequently contacting the first population of cells with a reagent composition comprising one or more detergents and a luciferase, wherein the reagent composition further comprises NaF; and with the proviso that, wherein the reagent composition maintains at least about 30% activity, as measured by luminescence after the reagent composition is combined with the sample, for at least one hour compared to the reagent composition's activity just after the luciferase is

combined with the one or more detergents, and with the proviso that wherein the one or more detergents present in the reagent composition are collectively able to reduce ATPase activity endogenous to the sample by at least about 25% relative to the sample's ATPase activity in the absence of the one or more detergents; and (c) detecting an amount of luminescence and (d) comparing the amount of luminescence in the first population to an amount of luminescence in a second population of cells as claimed in the present invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (571)272-0966. The examiner can normally be reached on Monday to Friday from 10 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Louise N. Leary
Primary Examiner
Art Unit 1654
January 6, 2005